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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,051	07/23/2001	Weenna Bucay-Couto	01-089	3728

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MAYER, FORTKORT & WILLIAMS, PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,051

Applicant(s)

BUCAY-COUTO ET AL.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19, 21-29, 31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-17, 19, 21-29, 31-33, 35 and 36 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,5,7-8,10-11,14,21-22,27-28,31-32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Schneider Inc. (EP 0879595 A2).

Schneider discloses a blood or a urine contacting device which may include a catheter, shunt or stent (all annular structures) including a reservoir of a polymer matrix and an antimicrobial/antibiotic agent within (see p.3:42-44) the polymer matrix and a surfactant region being a surfactant disposed over the reservoir on an outer surface of the medical device. See summary and p.2:14-15. The surfactant includes a surfactant polymer, see p.6:26-32. The surfactant is linked to the outer surface by interactions including hydrophobic, ionic and covalent (see p.6:40-p.7:30). The device may be made from polyurethane, see p.4:37-40. The agent is disposed within the polymer matrix at the time of formation of the polymer matrix (see p.4:6-8). The coating is stabilized to permit long-term release. See p.3:27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15,17,19, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider Inc. (EP 0879595 A2). Schneider discloses the above and a urine contacting device that includes a reservoir being a polymer matrix and an antimicrobial agent and a surfactant disposed on an outer surface of the device. However, Schneider fails to teach implanting the device (ureteral stent or catheter) within the body of a patient for at least three months.

At the time of the invention, it would have been obvious to include the step of implanting the device within the body of a patient for at least three months. Catheters, stent and shunts for urinary treatment are well known in the art and are commonly used in patients for extended periods of time including at least three months. The motivation for the incorporation would have been obvious in light of the disclosed use and common knowledge in the medical field. Furthermore, it is common in patients having long term catheterization to develop infections and the incorporation of the method step would have been done in order to solve a stated problem of the reference (see Background of the Invention).

Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider Inc. (EP 0879595 A2). Schneider discloses the above and incorporating the agent via dissolving or suspension but fails to include the method of co-casting, co-extruding or imbibing the agent within the polymer matrix.

At the time of the invention, it would have been obvious to substitute the methods above for the production method of Schneider. The motivation for the substitution would have been for the ease of manufacturing or production.

Claims 2-4, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider Inc. (EP 0879595 A2) in view of Velraeds and Millsap.

Schneider meets the claim limitations as described above but fails to include a biosurfactant. However, Velraeds and Millsap both disclose a biosurfactant for use with urine contacting devices for enhanced prevention of infection. At the time of the invention, it would have been obvious to incorporate the biosurfactant in order to further the prevention of infection, thereby making the device safer to the patient.

Claims 5-6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider Inc. (EP 0879595 A2) in view of Vacheethasane.

Schneider meets the claim limitations as described above but fails to include a surfactant polymer having a poly(vinyl amine) backbone and having hydrophilic poly(ethylene oxide) and hydrophobic hexanal side chains. However, Vacheethasane discloses surfactant polymers designed to suppress bacterial adhesion on biomaterials. The surfactant polymers include a polymer as claimed in claim 6. At the time of the invention, it would have been obvious to incorporate the surfactant polymer of Vacheethasane into the invention of Schneider to provide a surface with enhanced ability to prevent bacterial adhesion thereby increasing the safety of the device to the patient.

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Claims 9, 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider Inc. (EP 0879595 A2) in view of BD WO 99/32168.

Schneider meets the claim limitations as described above but fails to include an antimicrobial agent selected from triclosan, chlorhexidine, silver sulfadiazine, silver ions, benzalkonium chloride, zinc pyrithione and iodine. However, BD WO 99/32168 discloses a device for incorporating an antimicrobial agent into a coating on a medical device. The agent includes chlorhexidine and iodine, see p.6:15-17.

At the time of the invention, it would have been obvious to use the antimicrobial agent of BD WO 99/32168 into the invention of Schneider. Both devices are analogous in the art and are designed to solve the same problem (i.e. infections resulting from implanted medical devices); therefore, a combination is proper. Additionally, the motivation for the incorporation would have been in order to expand the application of the device to treat additional pathogens thereby enhancing the functioning of the device to more medical indications.

Allowable Subject Matter

Claim 13 is allowed.

Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Response to Arguments

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a reservoir which is adapted for the long term release of an antimicrobial agent over a period of three months) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the prior art delays release through the use of an ionic-surfactant-containing layer, rather than through varying the release characteristics of the polymeric reservoir layer as in the instant invention) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke Williams *CSW*.
January 13, 2004

Brian Casler
BRIAN CASLER
SUPERVISOR
TELEPHONE 703-308-3552
FAX 703-308-3552